Covid-19 mRNA vaccines were conditionally approved after a median duration of only 2 months follow-up. Due to the many unknowns of Covid-19 mRNA vaccine efficacy and safety, post-authorisation safety study requirements were specified under conditional marketing authorisation by EMA. All post-authorisation obligations apply in a legally binding manner and are evaluated by the EMA. The requirements are codified in Risk Management Plans written by the manufacturer and agreed upon with the regulator before authorisation, and they form an enforceable feature of the authorisation. https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_2390. 41231

On January 11, 2022 we submitted a FOI request to EMA which was only partially fulfilled. Our subsequent complaint 635/2022/PB was answered by the Case-handling Unit of the European Ombudsman on April 6, 2022 suggesting to submit an access to documents request to EMA.

Following the Ombudsman's advice, we filed an access to documents request aiming at the transparency of regulatory oversight of a mandated post-authorisiation safety study on the Pfizer/BioNTech vaccine BNT-162b2 (Comirnaty®) in pregnant women (ASK-114361). EMA responded to our request in two batches. Batch 1 (PRAC rapporteur's preliminary assessment report EMA/2296/2022) was released on June 27, 2022. Access to documents and individual participants' data (Batch 2) of Study C4591015 was denied on July 22, 2022: „documents not held by the agency".

We hereby submit a complaint against EMA's decision for review by the European Ombudsman. Considering EMA's regulatory oversight of conditional approval requirements we doubt that the requested documents are not held by EMA.

We must assume that the manufacturer's decision to stop enrollment into study C4591015 at only 348 women instead of the planned 4000 women was recognized by the agency as a severe violation of the post-authorisation requirements with respect to vaccine safety and efficacy in pregnancy. With a study size of only 10% of the originally planned participants, the aims of study C4591015 as specified in the Risk Management Plan cannot be achieved. Why is the study size crucial? A very recent independent analysis of SAE summary tables submitted to the FDA for emergency use approval estimated the risk of severe adverse events of special interest after mRNA vaccination at 12.5/10.000 (full vaccination with 2 doses) which exceeded the benefit risk reduction of hospitalization due to Covid-19 (3-4/10.000).[1]

If EMA really does not hold the related documents, the conclusion must be drawn that EMA does not enforce legally binding conditional approval requirements for mRNA vaccine safety and efficacy evaluation.

1) Fraiman, J. Erviti J, Jones M. et al. Serious adverse events of special interest following mRNA vaccination in randomized trials. https://ssrn.com/abstract=4125239

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